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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,412	01/29/2004	Stephen A. Johnston	UTSD:681USC1	2869

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LIU, SUE XU	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/767,412	JOHNSTON ET AL.	
	Examiner	Art Unit	
	Sue Liu	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41-63* is/are pending in the application.

4a) Of the above claim(s) *42,46 and 61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41, 43-45, 47-60, 62 and 63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

Claims 41-63 are currently pending;

Claims 42, 46, and 61 have been withdrawn.

Claims 41, 43-45, 47-60, 62, and 63 are being examined in this application.

Claim Amendments

1. The amendment and response filed on 4/27/06 has been fully considered and entered in the application.

Specification Objections Withdrawn

2. In light of applicant's amendments to the specification, the following objections as set forth in the previous office action are withdrawn:

A.) No brief description for each one of the Figure 1A, 1B, 1C, and 1D.

B.) The filing date for the US Application No. 09/001,157 should be 12/20/1997 on Page 2, line 2 of the specification. (See Specification Amendment filed on 1/29/2004.)

Claim Rejections Withdrawn

3. In light of applicant's amendments to the claim and persuasiveness of applicant's argument, the following objections as set forth in the previous office action are withdrawn:

A. Claims 50, and 54-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the instant claims, the word "about" is indefinite since the terminology does not appear to have been defined in the specification as to clearly state the

specific range that the recited number can vary. Therefore, no clear defined metes and bounds for the claimed subject matter are provided.

B. Claims 41, 43-45, 47-60, 62 and 63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections Maintained (112 1st)

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description Rejection

5. Claims 41, 43-45, 47-60, 62 and 63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The previous rejection is maintained for the reasons of record advanced on pages 4-6 of the office action mailed on 10/28/2005.

Discussion and Answer to Argument

6. Applicants traversed the above rejection under the first paragraph of 35 U.S.C. 112 with the following arguments:

I. Applicants argue that the interpretation of the claim as recited on pg 5 of the previous Office action is not accurate.

II. Applicants also argue that two gene libraries (*Mycoplasma* and *Listeria*) are disclosed in the specification instead only one as discussed in the previous office action. Applicants also argue the representative number of species are disclosed for the claimed genus of organisms and subjects.

7. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record):

To address applicant's first argument (I), because the claim language is broad and unclear, the claim can be interpreted variously. It is initially noted that applicants have not pointed out the alleged inaccuracy in the said claim interpretation. Applicant's interpretation of the claims (recited in 2nd para., pg 10 of the reply) are not in conflict with the claim interpretation of the previous office action.

To address applicant's second argument (II), the claim language is very broad and encompasses any organism that constitute as a pathogen, and any subject that can be vaccinated. Even though the instant specification recites two particular examples of organisms, from which the library of nucleic acids can be derived from, these organisms are different species of bacteria. The term pathogen encompasses an entire genus of vast numbers of organisms (such as viruses and fungi) that are different in structure and/or functions. As applicants have pointed out under MPEP 2163 (II)3,

> Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the

> necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus. See, e.g., Eli L illy. Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces.
> (emphasis added)

a show of possession of the claimed entire genus of "pathogens" through representative number of species must demonstrate common attributes or features of the claimed genus. The two examples of the bacteria species do not share common structures and/or functions with the other species (such as viruses and fungi) within the claimed genus of pathogens. Therefore, the instant specification has not provided representative number of species to demonstrate the possession of the entire genus of pathogens.

Furthermore, the instant specification also has not demonstrated the possession of the entire genus of subjects, which could be any animal. Similarly to the discussion regarding the claimed genus of pathogens, only one species (mouse) of the claimed genus of subjects is disclosed by the instant specification. The claimed genus of subjects encompasses any animals and human. The different animals would not share common attributes and/or features that would render one single example representative of the entire genus of subjects (animals). Therefore, the instant specification has not provided representative number of species to demonstrate the possession of the entire genus of subjects.

Claim Rejections Maintained (Double Patenting)

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 41, 43, 48, 50-60 and 62 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 52-65 of copending Application No. 10/023,437. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. The previous rejection is maintained for the reasons of record advanced on pages 7-9 of the office action mailed on 10/28/2005.

10. Claims 41, 43, 44, 48-52, 54-60 and 62 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 and 27-30 of U.S. Patent No. 5,703,057 (henceforward refers to as '057 patent). The previous rejection is

maintained for the reasons of record advanced on pages 7-9 of the office action mailed on 10/28/2005.

11. Claims 41, 43, 59-60, 62 and 63 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 6,410,241 B1 (henceforward refers to as '241 patent). The previous rejection is maintained for the reasons of record advanced on pages 7-9 of the office action mailed on 10/28/2005.

Discussion and Answer to Argument

12. Applicants state the following:

I. In regard to '057 patent, a terminal disclaimer will be submitted upon indication of allowable subject matter.

II. Regarding the '437 application, Applicants note that a tenninal disclaimer will be submitted upon indication of allowable subject matter, if needed in view of any issued claims from the '437 application.

III. Regarding the '241 patent, Applicants traverse as follows: Cited claims 1-28 of the '241 patent describe methods of screening open reading frames to determine their capability of generating an immune response in an animal. However, claim 1 (b) explicitly states that an introduced expression element is to be introduced into an animal without intervening cloning or bacterial propagation. No genetic library is being utilized for administration into a subject. In contrast, the claims of the present application require the administration of a genetic library into

a subject. Thus, applicants submit that the inventions as claimed are distinct, and respectfully request that the rejection be withdrawn.

13. Applicant's intention to submit Terminal Disclaimers to overcome the ODP rejections over the '057 patent, and the '437 application are acknowledged.

Applicant's arguments regarding the '241 patent have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record):

Applicant's argument that the '241 patent claims a method that explicitly states that an introduced expression element is to be introduced into an animal without intervening cloning or bacterial propagation, is irrelevant to the ODP rejection. The instant claimed method does not explicitly state that intervening cloning or bacterial propagation are required steps. The '241 patent claims "at least one linear or circular expression element into a cell within an animal", which reads on introducing a plurality of members of said library into an animal of the instant claimed method, because the term "at least one" would read on a plurality. There are no apparent differences between the instant claimed method and the method claimed by the '241 patent. Therefore, the obviousness type double patenting rejection over the '241 patent is still maintained.

Claim Rejections Maintained (102 art rejection-Lai reference)

Claim Rejections - 35 USC § 102

14. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

15. Claims 41, 43-45, 47-50, 54-56, 59 and 62 are rejected under **35 U.S.C. 102(b)** as being anticipated by Lai et al (Vaccine. Vol 12: 291-298; March, 1994). The previous rejection is maintained for the reasons of record advanced on page 10 of the office action mailed on 10/28/2005.

Discussion and Answer to Argument

16. Applicants traversed the above rejection with the following arguments:

Applicants argue that the Lai reference teach screening their genetic library *in vitro* (see e.g., p. 294 col. 1). Constructs (library members) that had been pre-selected based on the in vitro immunological screen were then introduced into an animal to study their immunogenicity. Thus, Lai et al. in no way teach the method of claim 1, in which the screen (claim 1, step (a)) is carried out *in vivo*.

17. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record):

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., in vivo selection or screening of genetic library) are not recited in the rejected claim(s). The instant Claim 1 recite a method step (Step a)) that include three sub-steps:

i.) obtaining a library comprising DNA or RNA sequences from a pathogen;

ii) introducing a plurality of members of said library into an animal; and

iii) selecting at least a first member from the library that elicits an immune response to identify said nucleic acid or antigen;

The last selection step (iii) does not require the procedure to be carried out *in vivo* as argued by the applicant. The claimed method step does not require the selection of a member from the library be carried out within the animal. Thus, the claimed invention can be interpreted as a method of first obtaining a nucleic acid through screening and then administering the nucleic acid to a subject.

Contrary to applicant's assertion, the Lai reference does teach a method of vaccinating a subject by first obtaining a nucleic acid and then administering the nucleic acid to a subject, as discussed in the previous office action. Lai et al teach screening a library of DNA constructs derived from *Mycoplasma pulmonis* (MP; a bacterial pathogen), and immunizing animals with selected constructs against MP (See Abstract). The reference teaches injecting bacterial suspension (containing plurality of plasmid constructs) into mice (Page 293, 2nd paragraph), which would read on administering a plurality of nucleic acids to a subject. The reference also teaches selecting four clones (page 293, 1st paragraph), and sequencing analysis to identify the insert in the plasmid construct (Page 295). This would read on selecting and identifying the nucleic acid.

Claim Rejections Maintained (102 art rejection-Coney reference)

Claim Rejections - 35 USC § 102

18. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

19. Claims 41, 45, 47, 48, 59, 60 and 62 are rejected under **35 U.S.C. 102(a)** as being anticipated by Coney et al (Vaccine. Vol 12: 1545-1550. 12/1994). The previous rejection is maintained for the reasons of record advanced on pages 11-12 of the office action mailed on 10/28/2005.

Discussion and Answer to Argument

20. Applicants traversed the above rejection under the second paragraph of 35 U.S.C. 112 with the following arguments:

Applicants argue the cited description of several DNA constructs encoding various HIV proteins does not describe use of a genetic library. Rather, it describes the use of pre-selected coding regions from only specific gp160 envelope glycoproteins, or gag or pol genes. These specific coding regions were not selected in vivo from a library of DNA or RNA sequences as recited in the current claims. Furthermore, applicants argue that the reference's screening for immunogenicity is not described to occur via a method of in vivo screening of a plurality of genetic library members.

21. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record):

Contrary to applicant's assertion, the several constructs encoding various HIV that were administered to mice, as taught by Coney et al (page 1546, right column, 3rd paragraph of the Coney reference), read on a library comprising DNA or RNA sequence from a pathogen. The

several constructs taught by Coney would constitute a plurality, hence, a library of multiple sequences.

Similar to the discussion over the Lai reference, Applicants argue that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., in vivo selection or screening of genetic library) are not recited in the rejected claim(s). As discussed above, the instant claim does not claim a method of selecting and identifying (i.e. screening) for a member of the library in an animal (in vivo), but the claim language encompasses in vitro selection. Therefore, the Coney reference anticipates the claimed invention as set forth in the previous office action.

Claim Rejections Maintained (103 art rejection)

Claim Rejections - 35 USC § 103

22. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

23. Claims 41, 43-45, 47-60, 62 and 63 are rejected under 35 U.S.C. 103(a) as being obvious over Lai et al (Vaccine. Vol 12: 291-298; March, 1994), in view of Felgner et al (US Patent No. 5,589,466). The previous rejection is maintained for the reasons of record advanced on pages 12-14 of the office action mailed on 10/28/2005.

Discussion and Answer to Argument

24. Applicants traversed the above rejection under the second paragraph of 35 U.S.C. 112 with the following arguments:

I. Applicants argue that both Lai and Felgner references do not teach every element of the claims, especially the references do not describe in vivo screening of a library of DNA constructs derived from *M. pulmonis*.

II. Applicants also argue the polynucleotide(s) screened in step (a) of the instant claim 1 is not isolated or identified prior to the screening step, but is among a plurality of library members.

25. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record):

I. In response to applicant's first argument, the cited references do teach all elements of the instant claimed invention. As discussed above, the Lai reference teaches all of the steps of the instant claimed method of vaccinating a subject. Lai et al teach screening a library of DNA constructs derived from *Mycoplasma pulmonis* (MP; a bacterial pathogen), and immunizing animals with selected constructs against MP (See Abstract). The Lai reference teaches introducing a plurality of members of said library such as inoculation of mice with bacterial suspension (Page 293, 2nd paragraph), which comprises plurality of DNA molecules. The Lai reference also teaches selecting a member of the library (picking individual bacteria colonies; pg 293, 2nd para. of the Lai reference). Therefore, Lai teaches all the steps recited in the instant claims.

Lai et al do not teach the DNA sequences of a pathogen is fused to a mammalian fusion gene (such as human growth hormone), and the expression construct contains a promoter. The reference also does not teach the range and/or specific amount of DNA that is injected into an animal. In addition, the reference also does not teach the DNA is chemically synthesized.

However, Felgner et al teach injecting human growth hormone fusion protein expression constructs into a mammal (a human). (See Example 18 and Claim 5) The reference further teaches the expression construct comprises a promoter sequence which can control the expression of the DNA in mammal. Furthermore, the reference teaches the benefit of polynucleotide encoding for a secretable therapeutic polypeptide (such as growth hormone) that is it can be released into the circulation to seek a metabolic target (Column 14, lines 5-15). The reference also teaches the general range of DNA to be injected into an animal (about 0.05 ug/kg to about 50 mg/kg), which will vary depending on the activity of the particular peptide. (Column 15, lines 40-53) The reference also teaches the DNA inserts can be synthesized directly due to the availability of automated nucleic acid synthesis equipment (Column 11, lines 15-21).

Therefore, the combination of the cited references (Lai and Felgner) teaches every elements of the instant claimed method.

II. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the polynucleotide(s) screened in step (a) of the instant claim 1 is not isolated or identified prior to the screening step, but is among a plurality of library members) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the

specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The instant claim does not necessarily require that the identities of the nucleic acid members be unknown within the library of DNA or RNA sequences from a pathogen. That is the claimed library can have members that have known identities such as the genes or DNA constructs taught by the Lai reference.

Conclusion

26. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached at 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 1639
7/5/2006

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